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APPLICATION NO. FILING DATE ATTORNEY DOCKET NO. FIRST NAMED INVENTOR CONFIRMATION NO. 09/935,390 08/22/2001 Jaime Escobedo PP-01369.103/200130.428C1 1981 7590 **EXAMINER** 01/28/2004 **Chiron Corporation** MITRA, RITA Intellectual Property R338 P.O. Box 8097 **ART UNIT** PAPER NUMBER Emeryville, CA 94662-8097 1653

DATE MAILED: 01/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)
	09/935,390	CHIRIAN CORP
Office Action Summary	Examiner	Art Unit
	Rita Mitra	1653
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply		
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.  - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.  - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.  - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).  - Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).		
Status  1) Responsive to communication(s) filed on 25 January 2002.		
, <del></del>	s action is non-final.	•
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213.		
Disposition of Claims		
<ul> <li>4)  Claim(s) 1-13 is/are pending in the application.</li> <li>4a) Of the above claim(s) is/are withdrawn from consideration.</li> <li>5)  Claim(s) is/are allowed.</li> <li>6)  Claim(s) is/are rejected.</li> <li>7)  Claim(s) is/are objected to.</li> <li>8)  Claim(s) 1-13 are subject to restriction and/or election requirement.</li> </ul>		
Application Papers		
9) The specification is objected to by the Examiner.  10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.  Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).  11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.		
Priority under 35 U.S.C. §§ 119 and 120  12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).		
<ul> <li>12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).</li> <li>a) All b) Some * c) None of:</li> <li>1. Certified copies of the priority documents have been received.</li> <li>2. Certified copies of the priority documents have been received in Application No.</li> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> <li>13) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet.</li> <li>37 CFR 1.78.</li> <li>a) The translation of the foreign language provisional application has been received.</li> <li>14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.</li> </ul>		
Attachment(s)	_	
<ol> <li>Notice of References Cited (PTO-892)</li> <li>Notice of Draftsperson's Patent Drawing Review (PTO-948)</li> <li>Information Disclosure Statement(s) (PTO-1449) Paper No(s)</li> </ol>	5) Notice of Informal F	/ (PTO-413) Paper No(s) Patent Application (PTO-152)

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## **DETAILED ACTION**

## Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-4, drawn to an isolated human protein having an amino acid sequence selected from the group consisting of amino acid sequences of SEQ ID NO: 20 to SEQ ID NO: 38; fragments thereof; fusion protein comprising the said sequences, classified in class 530, subclass 350; class 435, subclass 69.7 Should Group I be elected, applicants are required to select one sequence of amino acids of SEQ ID NOs: 20-38.
- II. Claim 5, drawn to a preparation of antibody specific for protein of claim 1; classified in class 530, subclass 387.1+.
   Should Group II be elected, applicants are required to select one sequence of amino acids of SEQ ID NOs: 20-38 of claim 1.
- III. Claims 6-12 drawn to an isolated subgenomic polynucleotide, having a nucleotide sequence selected from the group consisting of nucleic acid sequences of SEQ ID NO: 1 to SEQ ID NO: 19; an isolated gene corresponding to a cDNA sequence selected from the group consisting of nucleic acid sequences of SEQ ID NO: 1 to SEQ ID NO: 19; a DNA construct for expressing a human protein having an amino acid sequence selected from the group consisting of amino acid sequences of SEQ ID NO: 20 to SEQ ID NO: 38; recombinant host cells; method of producing said human proteins; classified in class 435, subclass 69.1; class 536, subclass 23.5.

Should Group III be elected, applicants are required to select one sequence of nucleic acid of SEQ ID NO: 1-19 of claim 6, and one sequence of amino acids of SEQ ID NOs: 20-38 of claim 1.

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IV. Claim 13, drawn to a method of identifying a secreted polypeptide which is modified by rough microsomes, comprising the steps of in vitro transcription and translation; classified in class 536, subclass 23.1, 24.1, 24.3; class 435, subclass 6 and 7.1.

The inventions are distinct, each from the other because of the following reasons:

The protein of group I is related to the antibody of group II by virtue of being the cognate antigen necessary for the production of antibody. Although the protein and antibody are related due to the necessary steric complimentarity of the two, they are distinct inventions because the protein can be used in another and materially different process from the use for production of the antibody, such as in a pharmaceutical composition in its own right, or to assay or purify the natural ligand of the protein if it is a receptor. Further, a protein and its cognate antibody are structurally and functionally distinct molecules with different amino acids.

Inventions I and III are related as product and process of making. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case, the protein product can be made by other materially distinct processes, such as purification from the natural source or by chemical synthesis. Therefore, the inventions are distinct.

Inventions I and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the polypeptide of group I is not necessary for the practice of nor does the group I use the method of Group IV. Therefore the inventions are distinct.

Inventions II and III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the

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Antibody of group II is a separate and distinct chemical entity from nucleic acid of group III. The nucleic acid does not encode the antibody of II and is not used for the practice of the method of Group III. Therefore the inventions are distinct.

Inventions II and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the method of preparation of antibody of group II and the polypeptide detection method of group IV are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects. Therefore the inventions are distinct.

Inventions III and IV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the protein made by the method of group III is not necessary for the practice of claimed detection method of group IV. Therefore the inventions are distinct.

The restriction requires for a selection of a single sequence of polynucleotide sequence and a single sequence of amino acid sequence because each sequence has a different chemical and physical property. For example the protein having the amino acid sequence of SEQ ID NO: 23 comprises a Kuntz type serine protease inhibitor domain spanning amino acids 68 to 122 of SEQ ID NO: 23 while SEQ ID NO: 20 contains a zinc-finger motif. Therefore, the use of each sequence in the method claims would have a different effect. Therefore each sequence is distinct from the other.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a diligently filed petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(h).

Applicant is advised that the response to this requirement to be complete must include an

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election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

A telephone call was made to Attorney Jane Potter on December 8, 2003, to request an oral election to the above restriction requirement, but did not result in an election being made.

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## Inquiries

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Rita Mitra whose telephone number is (703) 605-1211. The Examiner can normally be reached from 9:30 a.m. to 6:30 p.m. on weekdays. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Christopher Low, can be reached at (703) 308-2923. Papers related to this application may be submitted to Technology Center 1600 by facsimile transmission. Papers should be faxed to Technology Center 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Fax Center number is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Rita Mitra, Ph.D.

January 24, 2004

Chris bylan 8. /au

CHRISTOPHER S. F. LOW SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1800